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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,365	06/23/2006	Bengt Bjellqvist	PU03103	8056
22840 7590 04/14/2010 GE HEALTHCARE BIO-SCIENCES CORP. PATENT DEPARTMENT 101 CARNEGIE CENTER PRINCETON, NJ 08540				
EXAMINER				
BALL, JOHN C				
ART UNIT		PAPER NUMBER		
1795				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

melissa.leck@ge.com

Office Action Summary

Application No.

10/584,365

Applicant(s)

BJELLQVIST ET AL.

Examiner

J. CHRISTOPHER BALL

Art Unit

1795

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-12, 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-12, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Summary

1. This Office Action is based on the Amendment filed with the Office on January 19, 2010, regarding the BJELLQVIST et al. application.
2. Claims 1-6, 8-12, 14, and 15 are currently pending and have been fully considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1-6 and 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has been amended to recite, *inter alia*, "providing said acidic interval IPG (immobilized pH gradient) gel", but also goes on to recite "a hydrophilic support" to which a sample is subsequently applied. It is unclear, given the specific language of the claim in its current form if the recited "a hydrophilic support" is meant to be the provided said acidic interval IPG gel or is a different element altogether. For further examination purposes, it will be

assumed that the recited hydrophilic support and the acidic interval IPG gel are one and the same.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1, 2, 10, 12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over RICE et al. (WO 96/27787), submitted to the Office on an Information Disclosure Statement, in view of an article by GIANAZZA et al. ("Formulations for immobilized pH gradients including pH extremes", ELECTROPHORESIS, vol. 10, 1989, p. 806-808).

Regarding claims 1 and 2, RICE discloses a membrane loader for gel electrophoresis, wherein is taught a method for sample application to a gel, comprising:

placing a hydrophilic support (308, Figure 5b) between a cathode (206, Figure 5b) and the cathode side of a gel (Figure 5b), wherein the support can be celluloid, plastic nylon or nitrocellulose (lines 12-15, page 5), which are hydrophilic; and

applying the sample onto the hydrophilic support (lines 2-4, page 5), wherein the hydrophilic support is derivatized with positively charged groups (lines 16-18, page 5).

RICE does not explicitly teach providing an acidic interval IPG gel as a preswollen ready-to-go gel.

However, GIANAZZA teaches formulations of acidic interval IPG gels (A-E, Table 1, p. 807), where the gels are swollen for use (paragraph bridging p. 806 and 808).

At the time of the present invention, it would have been obvious to modify the method as taught by RICE to utilize an acidic interval IPG swollen gel as taught by GIANAZZA because IPG gels make it possible to perform isoelectric focusing separations.

Regarding claim 10, RICE teaches the loader membrane can have a varying thickness and thereby releasably retain more or less sample (lines 22-24,

page 8). Therefore, the sample applied can be of any amount including in preparative amounts.

Regarding claims 12, RICE discloses a kit comprising a positively charged (lines 16-18, page 5) sample applicator (308, Figure 5b) and a gel (220, Figure 5b).

RICE does not teach an IPG gel.

RICE does not explicitly teach providing an acidic interval IPG gel as a preswollen ready-to-go gel.

However, GIANAZZA teaches formulations of acidic interval IPG gels (A-E, Table 1, p. 807), where the gels are swollen for use (paragraph bridging p. 806 and 808).

At the time of the present invention, it would have been obvious to modify the method as taught by RICE to utilize an acidic interval IPG swollen gel as taught by GIANAZZA because IPG gels make it possible to perform isoelectric focusing separations.

Regarding claim 14, GIANAZZA teaches an acidic interval with pH between 2.5 and 5 (D and E, Table 1, p. 807), which encompasses the range from 3.5 to 5.

8. Claims 3-6, 8, 9, 11, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over RICE et al. (WO 96/27787), submitted to the Office on an Information Disclosure Statement, in view of an article by GIANAZZA et al. ("Formulations for immobilized pH gradients including pH extremes", ELECTROPHORESIS, vol. 10, 1989, p. 806-808) as applied to claims 1, 2, and 10 above, and further in view of CARLSSON et al. (US 6,528,322 B1).

Regarding claims 3-6, RICE, as modified by GIANAZZA, teaches the limitations of claim 1, as outlined above.

RICE teaches that the support can be positively charged (lines 16-18, page 5), which one of skill in the art would know could be obtained by cation groups. RICE does not explicitly teach cation groups.

However, CARLSSON discloses a method and apparatus for the separation of analytes via a matrix, wherein is taught a ligand/structure that can be introduced to the matrix (Col. 6, lines 19-21), where the ligand/structure comprise ion-exchange functional groups including anion exchangers (inherently cation groups), such as quaternary aminoethyl and diethyl aminoethyl (Col. 6, lines 44-49).

At the time of the present invention, it would have been obvious to one of ordinary skill in the art to modify the method as taught by RICE in functionalizing the support with either the quaternary aminoethyl and diethyl aminoethyl as

taught by CARLSSON because it would provide the positively charged surface that RICE recites for the support (RICE, lines 16-18, page 5).

Regarding claims 8 and 9, RICE, as modified by GIANAZZA, teaches the limitations of claim 1, as outlined above. RICE additionally teaches that the support can be formed from celluloid materials.

RICE does not explicitly teach the support is made from regenerated cellulose.

However, CARLSSON teaches matrices can be formed from regenerated cellulose (Col. 5, line 47-49), which would extend to the materials from which the ligand/structure can be formed. CARLSSON also teaches the ligand/structure comprise ion-exchange functional groups including anion exchangers such as quaternary aminoethyl and diethyl aminoethyl (Col. 6, lines 44-49), which quaternary ammonium would be logical substitute to a skilled artisan that would yield predictable results.

At the time of the present invention, it would have been obvious to one of ordinary skill in the art to modify the method as taught by RICE in forming the support from regenerated cellulose and functionalizing the support with either the quaternary aminoethyl and diethyl aminoethyl as taught by CARLSSON because it would provide the positively charged surface that RICE recites for the support (RICE, lines 16-18, page 5).

Regarding claim 11, RICE, as modified by GIANAZZA, teaches the limitations of claim 1, as outlined above.

RICE does not teach the method as a first step in 2D electrophoresis.

However, CARLSSON teaches a 2D electrophoresis (Col. 3, lines 19-30; Figures 2A-C).

At the time of the present invention, it would have been obvious to one of ordinary skill in the art to modify the method as taught by RICE to make the method the first step in a 2D electrophoresis process as taught by CARLSSON because it allows a better separation means versus a single dimension electrophoresis.

Regarding claim 15, RICE, as modified by GIANAZZA, teaches the limitations of claim 12.

RICE does not explicitly teach the support is made from regenerated cellulose.

However, CARLSSON teaches matrices can be formed from regenerated cellulose (Col. 5, line 47-49), which would extend to the materials from which the ligand/structure can be formed. CARLSSON also teaches the ligand/structure comprise ion-exchange functional groups including anion exchangers such as quaternary aminoethyl and diethyl aminoethyl (Col. 6, lines 44-49), which quaternary ammonium would be logical substitute to a skilled artisan that would yield predictable results.

At the time of the present invention, it would have been obvious to one of ordinary skill in the art to modify the method as taught by RICE in forming the support from regenerated cellulose and functionalizing the support with either the quaternary aminoethyl and diethyl aminoethyl as taught by CARLSSON because it would provide the positively charged surface that RICE recites for the support (RICE, lines 16-18, page 5).

Response to Arguments

9. Applicant's arguments, see Remarks, p. 5, filed January 19, 2010, with respect to claims 5, 6, 9, 15, and 17 have been fully considered and are persuasive. The objection of claims 5, 6, 9, 15, and 17 has been withdrawn.

10. Applicant's arguments, see Remarks, p. 5-6, filed January 19, 2010, with respect to the rejection(s) of claim(s) 1-6, 8-12, 14, and 15 under 35 USC 102(b) or 35 USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the newly found prior art, GIANAZZA et al.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. CHRISTOPHER BALL whose telephone number is (571)270-5119. The examiner can normally be reached on Monday through Thursday, 9 am to 5 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/
Supervisory Patent Examiner, Art Unit 1753

JCB
04/08/2010